

No. 20-5170

**IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

BRIAN WOODCOCK, et al.,

Plaintiffs-Appellants,

v.

CORRECT CARE SOLUTIONS, LLC, et al.,

Defendants-Appellees.

On Appeal from the U.S. District Court for the Eastern District of Kentucky,
No. 3:16-cv-00096, Honorable Gregory F. Van Tatenhove, U.S. District Judge

**BRIEF OF DRS. JOSEPH BICK, JOSEPH GOLDENSON, ROBERT B.
GREIFINGER, HOMIE RAZAVI, AND MARC STERN, THE HEPATITIS
EDUCATION PROJECT, THE INTERNATIONAL NETWORK ON
HEPATITIS IN SUBSTANCE USERS – PRISONS NETWORK, AND THE
NATIONAL VIRAL HEPATITIS ROUNDTABLE AS *AMICI CURIAE* IN
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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1(a), the Hepatitis Education Project, the International Network on Hepatitis in Substance Users – Prisons Network, and the National Viral Hepatitis Roundtable are not subsidiaries of any other corporation, and no publicly held corporation owns ten percent or more of each organization's stock.

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INTEREST OF *AMICI CURIAE*¹

Dr. Joseph Bick, MD, serves as Chief Medical Executive of the California Medical Facility within the California Department of Corrections and Rehabilitation. His clinical areas of expertise include HIV/AIDS, tuberculosis, viral hepatitis, and prison healthcare.

Dr. Joseph Goldenson, MD, served as Director of Jail Health Services for the San Francisco County Jail. He served as a member of the Board of Directors of the National Commission on Correctional Health Care and is past President of the California chapter of the American Correctional Health Services Association. He has served as a court-appointed expert on correctional medical care in several cases, including *Brown v. Plata*, 563 U.S. 493 (2011); *Wilkinson v. Austin*, 545 U.S. 209 (2005); and *Madrid v. Gomez*, 889 F. Supp. 1146 (N.D. Cal. 1995).

Dr. Robert B. Greifinger, MD, was the Deputy Commissioner and Chief Medical Officer of the New York State Department of Correctional Services. He was the principal investigator for the *Report to Congress: The Health Status of Soon-to-Be-Released Inmates*, and the *Report to Congress: Seizing Public Health Opportunities through Correctional Health Care*, both published in 2002. He edited the book *Public Health Behind Bars: From Prisons to Communities*

¹ All parties have consented to filing. No party's counsel authored this brief. No party or party's counsel, or any other person, other than the *amici curiae* or their counsel, contributed money to fund this brief.

(Springer, New York 2007) and served as co-editor of the *International Journal of Prisoner Health*.

Dr. Homie Razavi, PhD, MBA, is the Managing Director at the Center for Disease Analysis Foundation (CDAF) a non-profit dedicated to the global elimination of viral hepatitis. He has co-authored over 70 peer reviewed publications on elimination of hepatitis globally and is a frequent speaker on the subject. He is a fellow in the Society of Decision Professionals and a member of the American Association for the Study of Liver Diseases and European Association for the Study of the Liver. He is also a board member of the World Hepatitis Alliance (WHA) and the CDA Foundation.

Dr. Marc Stern, MD, MPH, served as Assistant Secretary for Health Services for the Washington State Department of Corrections. He is an assistant professor of health services at the University of Washington. He currently serves as a court-appointed expert in the case of *Parsons v. Ryan*, 754 F.3d 657 (9th Cir. 2014).

The Hepatitis Education Project is a non-profit organization that advocates for access to affordable, high-quality care to support all health needs and is committed to improving the health of underserved communities disproportionately impacted by viral hepatitis.

The International Network on Hepatitis in Substance Users – Prisons Network (INHSU Prisons) was established in 2019 as a special interest group for INHSU

members, with a focus on the prison setting. INHSU Prisons aims to connect healthcare providers, policy makers, health administrations, academics, and advocates from across the world to participate in scientific knowledge exchange and knowledge translation, and to advocate for health, including hepatitis C (HCV) prevention and care among people who use drugs and are incarcerated.

The National Viral Hepatitis Roundtable (NVHR) is a national coalition of organizations that work together with the goal of eliminating hepatitis B and C in the United States. NVHR is dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis.

BACKGROUND AND SUMMARY OF ARGUMENT

This appeal is one of the growing number of actions to argue that categorical denial of treatment to prisoners with chronic hepatitis C on the basis of an institutional policy violates the Eighth Amendment.² It is among the first to reach a court of appeals on the merits.

² *West v. Gobeille*, No. 2:19-cv-81, 2020 WL 1505677, at *1 (D. Vt. Mar. 30, 2020) (granting class certification and denying motion to dismiss in hepatitis C statewide inmate class-action where Vermont DOC allegedly refused to provide DAAs because of cost); *Molina v. Fla. Dep't of Corr.*, No. 4:19-cv-157, ECF No. 92 (N.D. Fla. Mar. 20, 2020) (denying motions to dismiss where inmate-plaintiffs alleged that Florida DOC denied them DAAs); *Pfaller v. Clarke*, No. 3:19-cv-00728, ECF No. 51 (E.D. Va. Mar. 11, 2020) (denying motions to dismiss where inmate-plaintiff alleged that Virginia DOC denied him DAAs); *Kruse v. Fisher*, No. 1:19-cv-00005 (E.D. Cal. Aug. 28, 2019) (denying motion to dismiss inmate-plaintiff's Eighth Amendment claim that California Valley State Prison refused to

The increase in such cases is not a coincidence—rather, it is the direct result of revolutionary advances in the treatment of the hepatitis C virus (HCV). The discovery of easy-to-use and remarkably effective direct-acting antivirals (DAAs) with minimal side effects has led not only to positive changes in medical outcomes that were previously impossible to achieve, but also to downstream changes in treatment guidelines and the medical standard of care. Since DAAs were introduced, standard-of-care guidelines have shifted, Medicaid programs have updated their treatment coverage policies, some prison systems have altered their practices, and foreign governments have instituted programs to cure the disease. Where, as here,

provide him with DAAs); *Lovelace v. Clarke*, No. 2:19-cv-75, 2019 WL 3728265 (E.D. Va. Aug. 7, 2019) (denying motions to dismiss where inmate-plaintiff alleged that Virginia DOC denied him DAAs); *Barfield v. Cook*, No. 3:18-cv-1198, 2019 WL 3562021 (D. Conn. Aug. 6, 2019) (certifying class of inmates who alleged that Connecticut DOC denied them DAAs); *Hoffer v. Inch*, 382 F. Supp. 3d 1288, 1315 (N.D. Fla. 2019) (holding Florida DOC's failure to treat prisoners with chronic HCV unconstitutional and entering permanent injunction for administration of DAAs); *Stafford v. Carter*, No. 1:17-cv-00289, 2018 WL 4361639, at *1 (S.D. Ind. Sept. 13, 2018) (granting summary judgment for inmate-plaintiffs as to their Eighth Amendment claim that Indiana DOC withheld DAAs from HCV-infected inmates); *Chimenti v. Wetzel*, No. 15-cv-3333, 2018 WL 3388305, at *1 (E.D. Pa. July 12, 2018) (denying summary judgment on claim that Pennsylvania DOC withheld DAAs from HCV-infected inmates); *Abu-Jamal v. Wetzel*, No. 3:16-cv-2000, 2017 WL 34700, at *1 (M.D. Pa. Jan. 3, 2017) (granting preliminary injunction for inmate-plaintiff with chronic HCV to be treated with DAAs).

an outmoded treatment policy persists despite these advances, parties have challenged that outdated policy through litigation.

Prior to 2011, the standard of care for treating HCV was based on using interferon, which mimicked a natural substance made by the body's white blood cells to aid the immune system.³ Interferon-based treatment had several problems, including variable responses in patients depending on a host of factors, an extended course of treatment, and, for many, severe side effects.⁴

Beginning in 2011 with the introduction of the first DAAs, HCV treatment improved radically. Gone are the varied responses; the new regimen yields a Sustained Virologic Response (SVR) rate higher than 90%.⁵ No longer does

³ Eni Williams, *What Are Interferons and How Do They Work?*, MedicineNet, https://www.medicinenet.com/interferon/article.htm#what_are_interferons_and_how_do_they_work (last visited Apr. 3, 2020); Stephen Holt, *What Are the Long-term Side Effects of Interferons for Hepatitis C?*, Hepatitis Central (Mar. 4, 2019), <https://www.hepatitiscentral.com/news/what-are-the-long-term-side-effects-of-interferons-for-hepatitis-c/>.

⁴ Dr. Daniel Murell, *Interferons for Hepatitis C: Understanding the Long-term Side Effects*, Healthline (June 5, 2018), <https://www.healthline.com/health/hepatitis-c/interferons-long-term-effects>.

⁵ Jennifer L. Horsley-Silva & Hugo E. Vargas, *New Therapies for Hepatitis C Infection*, Gastroenterology & Hepatology (Jan. 2017), Millennium Med. Pub., <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5390323/>. SVR refers to a test result indicating that the hepatitis C virus is no longer detectable in the body at least 12 weeks following treatment; it is “tantamount to a virologic cure.” AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), <https://www.hcvguidelines.org/evaluate/when-whom>.

treatment take 48 weeks; the standard course is now 8 to 12 weeks.⁶ Severe toxic side effects are absent; DAA treatment is well-tolerated. This sea-change in HCV treatment transformed the medical standard of care. However, some public agencies' HCV treatment policies fail to reflect this standard, often out of cost concerns. Nevertheless, cost is an improper consideration in the Eighth Amendment context,⁷ and it can be reduced through negotiated pricing. This Court should consider that dissymmetry—between the standard of care and the treatment policies at issue—in determining whether there is a question of material fact on whether Defendants have demonstrated deliberate indifference to a serious medical need.

Background on Hepatitis C. Hepatitis C is an easily transmitted liver disease resulting from HCV infection, which has devastating effects on those who contract it. Estimates suggest that 2 to 3 million people in the United States are living with the chronic form of this disease.⁸ For every 100 persons newly infected with HCV,

⁶ See AASLD/IDSA, HCV Guidance, *Recommendations for Testing, Managing and Treating Hepatitis C* (Dec. 10, 2019), <https://www.hcvguidelines.org/treatment-naive/simplified-treatment>.

⁷ If proven, such a rationale can constitute a constitutional violation on its own. See *Darrah v. Krisher*, 865 F.3d 361, 372 (6th Cir. 2017) (“When prison officials are aware of a prisoner’s obvious and serious need for medical treatment and delay medical treatment of that condition for non-medical reasons, their conduct in causing the delay creates a constitutional infirmity.” (quoting *Blackmore v. Kalamazoo City*, 390 F.3d 890, 899 (6th Cir. 2004))).

⁸ CDC, *Hepatitis C FAQs for Health Professionals*, <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited Apr. 3, 2020); U.S. Department of Health and Human

approximately 75 to 85 will develop chronic hepatitis C, a long-term illness that can lead to deadly liver problems.⁹ For instance, of those same 100 people, 10 to 20 will eventually develop cirrhosis of the liver, scarring that severely damages the liver's function and can result in liver cancer and liver failure.¹⁰

HCV is spread when blood from a person infected with the virus enters the body of another, for instance, through contact with a needle previously used by an individual with HCV or, less commonly, by sharing personal care items, through sexual contact, or by getting a tattoo or body piercing in an unregulated setting.¹¹

As it progresses, HCV causes severe liver damage, among the many effects that accompany a chronic inflammatory disease.¹² This progressive damage to the liver, called "fibrosis," is most commonly measured using ascending fibrosis scores of F0 (no scarring) to F4 (advanced scarring, or cirrhosis of the liver).¹³ Even if fibrosis never reaches an advanced stage, HCV puts patients at risk for mental

Services, *Basic Hepatitis C Information*, <https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-c-basics/index.html> (last visited Apr. 3, 2020).

⁹ CDC, *Hepatitis C FAQs for the Public*, <https://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last visited Apr. 3, 2020).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ See, e.g., AASLD/IDSA, *HCV Guidance, When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), <https://www.hcvguidelines.org/evaluate/when-whom>.

changes, fatigue, joint pain, depression, sore muscles, arthritis, various cancers, nerve damage, and jaundice, and may increase the risk of heart attack and diabetes.¹⁴

The Centers for Disease Control and Prevention (CDC) approximates that in 2016, HCV directly caused or contributed to 18,153 deaths in the United States, but believes that number to be an underestimate.¹⁵ In May 2016, the CDC compared hepatitis C to 60 other nationally significant infectious diseases, including HIV, tuberculosis, and pneumococcal disease, and found that HCV killed more Americans than the 60 others combined.¹⁶

Chronic hepatitis C disproportionately affects incarcerated individuals—by recent estimates, HCV is 17 to 23 times more prevalent among prisoners than the general population.¹⁷ Less than 1% of the U.S. population is incarcerated today, but

¹⁴ See Francesco Negro & Gamal Esmat, *Extrahepatic Manifestations in Hepatitis C Virus Infection*, 8 J. of Advanced Res. 85–87 (Mar. 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5272942/>; Krystian Ślusarz, et al., *Infection with Hepatitis C Virus as a Cause of Nervous System Disorders*, 9 J. of Educ., Health & Sport 230–40 (2019), <http://www.ojs.ukw.edu.pl/index.php/johs/article/download/7016/8741>.

¹⁵ CDC, *supra* n.9. See also CDC, *Hepatitis C Prevalence Estimates 2013-2016* (Nov. 6, 2018), <https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates.html>.

¹⁶ CDC, *Hepatitis C Mortality* (May 4, 2016), <https://www.cdc.gov/nchhstp/newsroom/2016/hcv-mortality.html>.

¹⁷ AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings* (Nov. 6, 2019), <https://www.hcvguidelines.org/unique-populations/correctional>.

30% of all people in the United States with HCV are in prison.¹⁸ HCV also disproportionately impacts African Americans, who comprise approximately 11% of the population but 25% of those with chronic hepatitis C.¹⁹ As early as 2012, the Surgeon General referred to viral hepatitis as a “silent epidemic.”²⁰

Hepatitis C Epidemic in Kentucky. Kentucky has been particularly hard-hit by the hepatitis C epidemic.²¹ More than 43,000 of the state’s 4.4 million residents have been diagnosed with hepatitis C,²² and estimates suggest that Kentucky’s rate

¹⁸ Aiden K. Varen, et al., *Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High But Declining*, Public Health Reports, at 187–95 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904899/>. See also AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings* (Nov. 6, 2019), <https://www.hcvguidelines.org/unique-populations/correctional>.

¹⁹ Francis Collins, *Hepatitis C Disparities among African Americans*, U.S. Department of Health & Human Services (Feb. 27, 2017), <https://www.hhs.gov/hepatitis/blog/2017/02/27/hepatitis-c-disparities-among-african-americans.html>.

²⁰ CDC, *Surgeon General’s Perspectives: Raising Awareness of Viral Hepatitis: National Hepatitis Testing Day, May 19*, https://www.cdc.gov/hepatitis/pdfs/surgeongeneral-phr_may-june2012.pdf (last visited Apr. 3, 2020).

²¹ Darla Carter, *Hepatitis C Project To Fight Infection In Kentucky, Greater Appalachia*, Louisville Future (Apr. 25, 2019), <https://louisvillefuture.com/archived-news/hepatitis-c-project-to-fight-infection-in-kentucky-greater-appalachia/>.

²² Commonwealth of Kentucky Cabinet for Health and Family Services, *Kentucky Holds Statewide Hepatitis C Elimination Meeting*, (July 29, 2019), <https://chfs.ky.gov/News/Documents/nrhepcmeeting.pdf>; Ashleigh Mills, *Rural Clinics Reach Out to Kentuckians to Treat Hepatitis C*, Spectrum News 1 (May 17, 2019), <https://spectrumnews1.com/ky/louisville/news/2019/05/17/hepatitis-c-in-kentucky>.

of infection leads the country at upwards of 7 times the national average.²³ The opioid crisis has only exacerbated the problem.²⁴ The prevalence of HCV in Kentucky has also compounded an existing health crisis—Kentucky has the highest rate of cancer and cancer-related deaths in the United States.²⁵

In response, Kentucky and its leading healthcare providers have acknowledged the epidemic's severity and have devoted resources to its elimination in the community. Kentucky's Department of Public Health "organiz[ed] the state's leaders in HCV treatment in order to develop a comprehensive and statewide strategy to eliminate Hepatitis C."²⁶ The University of Kentucky, along with the National Cancer Institute and National Institute on Drug Abuse, launched a three-year, \$15 million study aimed at removing barriers to DAAs in heavily affected counties.²⁷ Doctors at the University have called DAAs "miracle drug[s]."²⁸

²³ Louisville-Jefferson County Metro Government, *Health & Wellness: Hepatitis C*, <https://louisvilleky.gov/government/health-wellness/hepatitis-c> (last visited Apr. 3, 2020).

²⁴ Carter, *supra* n.21.

²⁵ Allison Perry, *\$15 Million Hepatitis C Study Launched In Kentucky*, Richmond Register (Jan. 23, 2020), https://www.richmondregister.com/news/million-hepatitis-c-study-launched-in-kentucky/article_bc7983f2-d3f2-5cd7-b297-a8f5bda9cbff.html.

²⁶ Commonwealth of Kentucky Cabinet for Health and Family Services, *supra* n.22.

²⁷ Perry, *supra* n.25.

²⁸ *Id.*

Similarly, the University of Louisville Hospital noted that “significant advances . . . have paved the way for 99% cure rates,” regardless of disease progression,²⁹ and the Hospital worked with Kentucky’s governor to launch a five-year, multi-million-dollar initiative to eradicate the disease.³⁰ Several other organizations, including county health departments, split a \$1 million grant to fight the spread of HCV³¹ and, at the recommendation of the Pharmacy and Therapeutics Advisory Committee, Kentucky’s Department for Medicaid Services Fee-for-Service program eliminated minimum liver damage and sobriety requirements for first-time DAA recipients covered by Medicaid.³²

At the same time, however, and despite these momentous advances, the Kentucky Department of Corrections (“KDOC”) has maintained arbitrary conditions

²⁹ University of Louisville Hospital, *Hep C Center*, <https://uoflhospital.org/services/hep-c-center> (last visited Apr. 3, 2020).

³⁰ Carter, *supra* n.21.

³¹ Kyeland Jackson, *Kentucky Organizations Get \$1 Million To Fight Hepatitis C*, 89.3 WFPL (Oct. 1, 2019), <https://wfpl.org/kentucky-organizations-get-1-million-to-fight-hepatitis-c/>.

³² Hepatitis C: State of Medicaid Access Report Card, *Kentucky* (2017), https://stateofhepc.org/wp-content/themes/infinite-child/reports/HCV_Report_Kentucky.pdf. Kentucky operates a Fee-for-Service program, which covers approximately 9% of Medicaid recipients, and contracts with Managed Care Organizations (MCOs), which cover the remaining 91% of recipients. Of the five MCOs Kentucky contracts with, one has removed minimum liver damage requirements for most DAA treatments, and another has removed them for all treatments.

on treatment, which have resulted in delays or outright denials, thereby risking irreversible damage and, in some cases, death. Given the churn of Kentuckians into and out of the state's prisons, KDOC's failure to treat the disease in its prisons also undercuts the state's efforts to eradicate it outside of them. While the standard of care in Kentucky dictates that infected individuals be administered curative drugs, this treatment still remains beyond reach for many of those in KDOC's custody.

ARGUMENT

I. THE INTRODUCTION OF DIRECT-ACTING ANTIVIRALS REVOLUTIONIZED HCV TREATMENT

Prior to 2011, interferon-based treatment for HCV required a series of “grueling shots” and “pills that gave patients flu-like symptoms.”³³ These side effects, coupled with a prolonged course of treatment and a cure rate of only 40% to 50%, posed significant problems.³⁴ Indeed, whether to provide interferon treatment was a debated question of medical judgment.³⁵

³³ Associated Press, *FDA Approves New Drug to Treat Hepatitis C*, CBS News (Aug. 4, 2017), <https://www.cbsnews.com/news/fda-approves-mavyret-abbvie-drug-to-treat-hepatitis-c/>.

³⁴ FDA, *Hepatitis C Treatments Give Patients More Options* (Mar. 4, 2017), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm>.

³⁵ See, e.g., *Howze v. Hickey*, No. 10-cv-094, 2011 WL 673750, at *10 (E.D. Ky. Feb. 17, 2011) (“[T]his case is simply a situation where there is a disagreement among medical professionals regarding the medical appropriateness of interferon therapy for plaintiff's Hepatitis C condition.”).

This all changed around 2011, when the U.S. Food & Drug Administration (FDA) began approving a series of DAAs.³⁶ Later, in 2013, the FDA’s approval of sofosbuvir (brand name Sovaldi®) marked the “advent of interferon-free treatments for hepatitis C” and “a landmark shift” in the treatment of the disease.³⁷ Since December 2013, the FDA has approved additional DAAs to treat hepatitis C.³⁸ The FDA has called these advances in HCV treatment “transformative”³⁹ and “breakthrough therapies.”⁴⁰ New DAAs “have double[d] the viral cure rates—90% to 100%—in just [] 12 weeks’ time.”⁴¹ In fact, medical experts have identified the development of DAAs used to treat HCV as one of the “biomedical breakthroughs”

³⁶ Ayman Gedday, et al., *Direct Acting Anti-hepatitis C Virus Drugs: Clinical Pharmacology and Future Direction*, 5 J. of Transnat’l Int’l Med. 8, 8–9 (Mar. 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490957/pdf/jtim-05-008.pdf>.

³⁷ Richard Knox, *Treatments: FDA Expected To Approve New, Gentler Cure for Hepatitis C*, NPR (Dec. 5, 2013), <https://www.npr.org/sections/health-shots/2013/12/05/248934833/fda-set-to-approve-hepatitis-drug>.

³⁸ See, e.g., James Myhre & Dennis Sifris, *FDA-Approved Hepatitis C Drugs*, Verywell Health (Jan. 13, 2020), <https://www.verywellhealth.com/list-of-approved-hepatitis-c-drugs-3576465>.

³⁹ FDA, *supra* n.34.

⁴⁰ FDA News Release, *FDA Approves Sovaldi for Chronic Hepatitis C*, U.S. Department of Health & Human Services (Dec. 9, 2013), <https://www.hhs.gov/hepatitis/blog/2013/12/09/fda-approves-sovaldi-for-chronic-hepatitis-c.html>.

⁴¹ FDA, *supra* n.34.

of the past decade, which “[f]rom a combined economic and public-health standpoint . . . may outstrip just about anything else” in the past ten years.⁴²

II. THE STANDARD OF CARE IS THAT NEARLY ALL CHRONIC HCV PATIENTS SHOULD BE TREATED

Because of the effectiveness of DAAs, the standard of care is that virtually all patients with chronic hepatitis C should be treated. This standard is articulated by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in published treatment guidelines. AASLD has over 5,000 members, including physicians, scientists, medical students, residents, and other healthcare professionals who work in hepatology and related areas.⁴³ IDSA comprises over 12,000 physicians, scientists, and health experts who specialize in infectious diseases.⁴⁴ The AASLD/IDSA guidelines are developed and

⁴² See, e.g., Max Nisen, *The 2010s Were a Decade of Drug Breakthroughs*, L.A. Times (Dec. 30, 2019), <https://www.latimes.com/business/story/2019-12-30/drug-breakthroughs-of-the-2010s>; Christina Farr, *These Biomedical Breakthroughs of the Decade Saved Lives and Reduced Suffering*, CNBC (Dec. 28, 2019), <https://www.cnbc.com/2019/12/27/biomedical-breakthroughs-of-the-2010s-crispr-hep-c-treatment-prep.html>.

⁴³ See AASLD, *2017 Annual Report* at 1–3 (Jan. 2017), <https://www.aasld.org/sites/default/files/2019-05/2018-AASLD-AnnualReport-Interactive.pdf>.

⁴⁴ IDSA, *Mission & Values*, <https://www.idsociety.org/about-idsa/mission-values/> (last visited Apr. 3, 2020).

maintained by a panel of HCV experts.⁴⁵ The CDC refers health professionals who treat chronic hepatitis C patients to the AASLD/IDSA guidelines and recognizes that the guidelines are “evidence-based, expert-developed recommendations for hepatitis C management.”⁴⁶ Moreover, in March 2020, the U.S. Preventive Services Task Force, an independent panel of experts appointed by the U.S. Department of Health and Human Services, relied on the AASLD/IDSA guidelines in a report that recommended screening for HCV in all adults ages 18 to 79 to “enable more individuals to seek curative treatment sooner,” because “more people can benefit . . . than ever before.”⁴⁷ Inarguably, the guidelines are the most “credible source of unbiased guidance on how best to treat [healthcare practitioners’] patients with HCV infection.”⁴⁸

⁴⁵ AASLD/IDSA, HCV Guidance, *Methods* (Nov. 6, 2019), <https://www.hcvguidelines.org/contents/methods>.

⁴⁶ CDC, *Hepatitis C FAQs for Health Professionals*, <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited Apr. 3, 2020).

⁴⁷ See U.S. Preventive Services Task Force, *U.S. Preventive Services Task Force Issues Final Recommendation Statement on Screening for Hepatitis C in Adolescents and Adults* (Mar. 2, 2020), <https://www.hhs.gov/hepatitis/blog/2020/03/04/uspstf-issues-updated-hepatitis-c-screening-recommendation.html>.

⁴⁸ AASLD/IDSA, HCV Guidance, *About the Guidance*, <https://www.hcvguidelines.org/about> (last visited Apr. 3, 2020). The AASLD/IDSA guidelines are widely cited as authoritative. See U.S. Department of Veteran Affairs (Aug. 27, 2018), *Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations*, <https://www.hepatitis.va.gov/pdf/treatment-considerations-2018-08-27.pdf> (noting that the AASLD/IDSA guidelines constitute the “current best practices in the treatment of chronic HCV”); Kaiser Permanente, *Hepatitis C Screening Guideline*

The guidelines state: “Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure and, as such, is expected to benefit nearly all chronically infected persons.”⁴⁹ They add that “from a medical standpoint, data continue to accumulate that demonstrate the many benefits, both intrahepatic [within the liver] and extrahepatic [outside of the liver], that accompany HCV eradication.”⁵⁰ Therefore, the guidelines “recommend treatment for all patients with chronic HCV infection,” except for the small subset with “a short life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy.”⁵¹ Accordingly, once it is confirmed

(Sept. 2016), <https://wa.kaiserpermanente.org/static/pdf/public/guidelines/hepatitis-c.pdf> (Sept. 2016), <https://wa.kaiserpermanente.org/static/pdf/public/guidelines/hepatitis-c.pdf> (“The [AASLD] and the [IDSA] have updated their published guidance to recommend HCV treatment for patients at all risk levels.”); Kentucky Cabinet for Health and Family Services, *KY Hepatitis Connections*, <https://chfs.ky.gov/agencies/dph/dehp/idb/Documents/KYHepatitisConnectionDecember2013.pdf> (last visited Apr. 3, 2020) (Kentucky Department of Public Health newsletter citing AASLD’s conclusion that successful DAA treatment “reduces the risk of liver cancer and death, but most remain untreated”).

⁴⁹ AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), <https://www.hcvguidelines.org/evaluate/when-whom> (emphasis added).

⁵⁰ *Id.*

⁵¹ *Id.* (emphasis added).

that a patient has hepatitis C, the recommended course of action in all but the most limited of circumstances is treatment with DAAs.⁵²

By contrast, institutional treatment guidelines, such as those at issue here, may recommend that doctors “monitor” patients that have tested positive and base treatment decisions on fibrosis scores (scarring levels), which is inconsistent with the standard of care reflected in the AASLD/IDSA guidelines. When a chronic illness has a known and available cure, passive “monitoring” does not constitute treatment, but the absence of it.⁵³ In particular, because the standard of care is that nearly all individuals with chronic hepatitis C should be treated and because fibrosis estimates are not always sufficiently sensitive, it is no longer appropriate to rely upon fibrosis scores to “monitor” and determine who should and should not be treated.

⁵² With regard to testing for the presence of HCV infection, the AASLD/IDSA guidelines recommend periodic testing of “persons with ongoing risk factors for HCV exposure,” including incarceration. *See* AASLD/IDSA, HCV Guidance (Nov. 6, 2019), *HCV Testing and Linkage to Care*, <https://www.hcvguidelines.org/evaluate/testing-and-linkage>.

⁵³ *See Postawko v. Mo. Dep’t of Corr.*, No. 2:16-cv-04219, 2017 WL 1968317, at *7 (W.D. Mo. May 11, 2017), *aff’d*, 910 F.3d 1030 (8th Cir. 2018) (“[A]dopting a monitoring policy instead of treatment and waiting to see just how much the inmate’s health may deteriorate is not permissible.”); *B.E. v. Teeter*, No. c16-227, 2016 WL 3033500, at *3 (W.D. Wash. May 27, 2016) (crediting plaintiffs’ argument that “mere ‘monitoring’ is not an equally effective treatment because ‘waiting until a Medicaid enrollee’s liver is damaged before providing treatment is harmful to his/her health and significantly increases the risk of both morbidity and mortality’”).

The guidelines indicate that treating patients at early stages of the disease is particularly beneficial, noting that “[i]nitiating therapy in patients with lower-stage fibrosis augments the benefits of SVR” and that “[t]reatment delay may decrease the benefit of SVR.”⁵⁴ Initiating treatment early is also important because “[f]ibrosis progression is variable across different patient populations as well as within the same individual over time.”⁵⁵ Relatedly, “[m]any of the components that determine fibrosis progression and development of cirrhosis in an individual are unknown.”⁵⁶ This is particularly important, as here, in the context of a certified class. While prison officials may rest their factual contentions on the specific medical records of individual named plaintiffs, population-level medical literature concerning fibrosis progression shows beyond argument that some unidentified absent class members

⁵⁴AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), <https://www.hcvguidelines.org/evaluate/when-whom>; see also American Society of Addiction Medicine, *Public Policy Statement on Hepatitis C Infection* (Apr. 5, 2017), <https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2017/04/11/hepatitis-c>.

⁵⁵ *Id.* See also Javier A. Cepeda, et al., *Increased Mortality Among Persons With Chronic Hepatitis C With Moderate or Severe Liver Disease: A Cohort Study*, 65 *Clinical Infectious Diseases* 235, 241 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5850450/> (“Withholding medical treatment based on disease stage implies that there is a ‘safe’ disease stage. Additionally, it is assumed that the ‘safe’ stage and transitions out of that stage can be accurately detected . . . [L]iver fibrosis estimates cannot differentiate mild from moderate fibrosis with sensitivity >80%. Likewise, progression of liver fibrosis was not predicted with sufficiently high diagnostic accuracy in most other studies.”).

⁵⁶ *Id.*

will suffer significant medical consequences in the absence of early treatment, including ongoing extrahepatic effects, risk of irreversible liver damage, and heightened risk of future liver disease and cancer.⁵⁷ Moreover, it is clear that individuals who have been cured of chronic hepatitis C can no longer transmit the virus to others.⁵⁸ As such, due to the lack of sensitivity of leading liver fibrosis estimates, there is no “safe stage” of hepatitis C during which treatment can be delayed while “monitoring” and attempting to guarantee that the patient suffers no adverse consequences.⁵⁹ Courts across the country have recognized this standard of care.⁶⁰

⁵⁷ See *supra* nn.47–52 and accompanying text.

⁵⁸ Behzad Hajarizadeh, et al., *Hepatitis C Treatment as Prevention: Evidence, Feasibility, and Challenges*, 1 *Lancet Gastroenterology & Hepatology* P317-27 (2016), [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(16\)30075-9/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(16)30075-9/fulltext).

⁵⁹ See *id.*

⁶⁰ See, e.g., *Postawko v. Mo. Dep’t of Corr.*, 910 F.3d 1030, 1034 (8th Cir. 2018) (“The medical standard of care put forward by organizations such as the Infectious Diseases Society of America and the American Association for the Study of Liver Diseases now recommends that almost all persons with chronic HCV receive DAA drug treatment.”); *Stafford v. Carter*, No. 1:17-cv-00289, 2018 WL 4361639, at *9 (S.D. Ind. Sept. 13, 2018) (“The [AASLD/IDSA] guidance is the national standard of care with respect to the treatment of patients with HCV.”); *Hoffer v. Jones*, 290 F. Supp. 3d 1292, 1296 (N.D. Fla. 2017) (“[T]he present-day standard of care is to treat chronic-HCV patients with DAAs as long as there are no contraindications or exceptional circumstances. It is inappropriate to only treat those with advanced levels of fibrosis.”); *Roberts v. Wilson*, No. 3:15-cv-1607, 2017 WL 8727155, at *2 (M.D. Pa. Sept. 27, 2017) (“The use of DAADs for the treatment of Hepatitis C is the new standard of care in the medical community, and is currently recommended

Healthcare coverage, policies, and practices also reflect this shift in available medicines and recognize that nearly all chronic HCV patients should be treated:

Medicaid. In 2015, the Centers for Medicare & Medicaid Services (CMS) issued a letter to state Medicaid coordinators characterizing DAAs for patients with HCV as “effective, clinically appropriate, and medically necessary” and rebuking states for “unreasonably restrict[ing] access” to DAAs by “limiting treatment” to beneficiaries with F3 or F4 fibrosis scores.⁶¹

In response, several state Medicaid programs removed barriers to treatment. Significantly, the state whose very regulations are at issue has broadened Medicaid coverage for hepatitis C treatment: As of November 2017, Kentucky’s Department for Medicaid Services Fee-for-Service program eliminated minimum liver damage and sobriety requirements for first-time DAA recipients covered by Medicaid.⁶²

Where state Medicaid programs did not voluntarily conform their policies to the standard of care, courts have repeatedly condemned their inaction. For example,

for treatment of all stages of Hepatitis C, except for those who are terminally ill.”), *R. & R. adopted*, 2018 WL 1583543 (M.D. Pa. Mar. 30, 2018); *Abu-Jamal v. Wetzel*, No. 3:16-cv-2000, 2017 WL 34700, at *18 (M.D. Pa. Jan. 3, 2017).

⁶¹ CMS, *Assuring Medicaid Beneficiaries Access to Hepatitis (HCV) Drugs*, U.S. Department of Health & Human Services, Release No. 172 (Nov. 5, 2015), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf>.

⁶² *See supra* n.32.

in May 2016, a federal district court in Washington ordered the state's Medicaid program to cover prescription medications for hepatitis C without regard to fibrosis score.⁶³ This decision ended Washington's policy of denying coverage to patients with mild liver scarring (fibrosis scores of F0 through F2) who were not diagnosed with any other diseases. In June 2016, in response to a formal litigation demand, Delaware's Division of Medicaid and Medical Assistance revoked categorical coverage exclusions that restricted treatment to those with significant liver damage or cirrhosis.⁶⁴ That same month, Florida expanded access to hepatitis C treatment by removing the fibrosis score restrictions.⁶⁵ Under its previous policy, insurers were prohibited from reimbursing treatment costs unless the patient had advanced liver scarring (an F3 or F4 score).⁶⁶ In January 2019, Iowa, one of the most

⁶³ See *B.E. v. Teeter*, Case No. c16-227, 2016 WL 3033500, at *1, *6 (W.D. Wash. May 27, 2016).

⁶⁴ Center for Health Law & Policy Innovation at Harvard Law School, *In Face of Class Action Lawsuit, Delaware Medicaid Removes Unlawful Restrictions to the Cure for the Hepatitis C Virus* (June 8, 2016), <https://www.chlpi.org/in-face-of-class-action-lawsuit-delaware-medicaid-removes-unlawful-restrictions-to-the-cure-for-the-hepatitis-c-virus/>.

⁶⁵ Associated Press, *Florida Changes Hep C Drug Policy for Medicaid*, NBC Miami (June 1, 2016), <https://www.nbcmiami.com/news/local/Florida-Changes-Hep-C-Drug-Policy-for-Medicaid-381573511.html>.

⁶⁶ *Id.*

restrictive states in terms of treating hepatitis C,⁶⁷ expanded its Medicaid care to include patients with moderate scarring (a fibrosis score of F2)—a change from its previous policy of restricting care to those with advanced liver scarring (scores of F3 or above).⁶⁸ In February 2019, Indiana Medicaid reached an agreement in federal court to remove all restrictions based on the severity of the disease.⁶⁹ Similarly, in April 2019, the U.S. District Court for the District of Kansas approved a class settlement removing all fibrosis score restrictions from the Kansas Medicaid coverage policy.⁷⁰

⁶⁷ In a 2017 nationwide analysis conducted by the Center for Health Law and Policy Innovation at Harvard Law School and the National Viral Hepatitis Roundtable, Iowa received a grade of D. The report noted that with Iowa’s “severe restrictions,” “very few people with hepatitis C have access to treatment.” Hepatitis C: State of Medicaid Access Report Card, *Iowa* (2017), https://stateofhepc.org/wp-content/themes/infinite-child/reports/HCV_Report_Iowa.pdf.

⁶⁸ Iowa Department of Human Services, *Informational Letter No. 966-MC-FFS* (Nov. 28, 2018), https://dhs.iowa.gov/sites/default/files/1966-MC-FFS_IowaMedicaidPharmacyProgramChanges.pdf?122020190757.

⁶⁹ Marilyn Odendahl, *Indiana Agrees to Provide Hepatitis C Drugs to More Medicaid Recipients*, *The Indiana Lawyer* (Feb. 19, 2019), <https://www.theindianalawyer.com/articles/49505-indiana-agrees-to-provide-hepatitis-c-drugs-to-more-medicare-recipients>.

⁷⁰ See ACLU, *The ACLU of Kansas Settles Hep-C Lawsuit* (Apr. 30, 2019), <https://www.shb.com/-/media/press-releases/2019/press-release-aclu-shook-hep-c.pdf?la=en> (describing settlement in *Harper v. Andersen*, No. 18-4008-DDC-GEB (D. Kan. filed Feb. 15, 2018)).

Taken as a whole, there is an unmistakable trend to remove illegal coverage restrictions on DAA treatment in state Medicaid programs. The National Viral Hepatitis Roundtable study of this trend reveals that, in the past five years, such restrictions have been removed in more than 30 states through voluntary cessation, policy reform, and litigation.⁷¹

International Standards. The World Health Organization (WHO) recommends treating all persons with chronic hepatitis C over the age of 12 with DAAs, “irrespective of disease stage.”⁷² WHO reasoned that “[e]xpanding treatment to the general population is cost-effective” and cited Egypt as an example.⁷³ Egypt, which has “one of the world’s highest incidence rates of hepatitis C—about 7 percent of its 90m population,” began an aggressive program to eliminate hepatitis C using DAAs and treated nearly 1 million hepatitis C patients in two years.⁷⁴ One study

⁷¹ See National Viral Hepatitis Roundtable & Center for Health Law & Policy Innovation, *Hepatitis C: The State of Medicaid Access*, https://www.chlpi.org/wp-content/uploads/2013/12/HCV_State-of-Medicaid-Access_November-2019-fix.pdf (last visited Apr. 3, 2020).

⁷² WHO, *Guidelines for the Care and Treatment of Persons Diagnosed with Chronic Hepatitis C Virus Infection* at xiii (July 2018), <https://apps.who.int/iris/bitstream/handle/10665/273174/9789241550345-eng.pdf?ua=1>.

⁷³ *Id.* at 19.

⁷⁴ Heba Saleh, *Egypt Combats Hepatitis C Epidemic with State-run Scheme*, Financial Times (Jan. 22, 2017), <https://www.ft.com/content/d1e18e96-d81b-11e6-944b-e7eb37a6aa8e>.

found that the use of DAAs in Egypt led to HCV suppression in nearly all treated patients,⁷⁵ and experts say Egypt could serve as the model for the rest of the world.⁷⁶ Further, the European Association for the Study of the Liver (EASL) recommends that all patients with HCV be treated, and the Canadian Association for the Study of Liver indicates that there is no medical justification for restrictions.⁷⁷

Prisons. A similar trend is occurring across the country as state corrections departments face judicial scrutiny under the Eighth Amendment over their HCV treatment policies. For example, the New York Department of Corrections increased its spending on prescription drugs from fiscal 2013 through 2015, which state officials attributed mostly to purchases of new hepatitis C medications.⁷⁸ New York

⁷⁵ See Ahmed Nagaty, *Real-life Results of Sofosbuvir based Therapy in Chronic Hepatitis C -naïve and -experienced Patients in Egypt*, PLOS One (Oct. 5, 2017), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0184654> (finding an overall sustained virologic response rate of 97.1%).

⁷⁶ Saleh, *supra* n.74.

⁷⁷ See EASL, *EASL Recommendations on Treatment of Hepatitis C 2018*, J. of Hepatology 1, 6 (2018), <https://easl.eu/wp-content/uploads/2018/10/HepC-English-report.pdf>; Hemant Shah, et al., *The Management of Chronic Hepatitis C: 2018 Guideline Update from the Canadian Association for the Study of the Liver*, 190 CMAJ E677, E679 (2018), <https://www.cmaj.ca/content/190/22/E677>.

⁷⁸ Pew Charitable Trusts, *Prison Health Care: Costs and Quality* at 16 (Oct. 2017), http://www.pewtrusts.org/~media/assets/2017/10/sfh_prison_health_care_costs_and_quality_final.pdf.

has treated more than 600 inmates with DAAs.⁷⁹ In May 2017, “[b]ecause of advances in medicine,” Wisconsin treated “more than 200 inmates” with DAAs in less than a year.⁸⁰ Officials at Wisconsin’s DOC indicated that the state increased the number of inmates receiving treatment from 72 in 2016 to 249 through spring 2017 because “pills with higher success rates and fewer side effects landed on the market and medical professionals shifted their recommendations to promote earlier treatment.”⁸¹ In California, the state’s 2018 budget allotted \$176 million to treat all of its inmates with hepatitis C over a three-year period.⁸² And earlier this year, the governor of New Mexico proposed a budget calling for \$30 million in funding for treatment of HCV, with the expectation that most inmates will be cured by 2024.⁸³

⁷⁹ Beth Schwartzapel, *Prisons Are Spending Millions on a Pricey New Drug*, Business Insider (Oct. 14, 2016), <http://www.businessinsider.com/prisons-are-spending-millions-on-a-pricey-new-drug-2016-10>.

⁸⁰ Keegan Kyle, *Wisconsin Prisons Spend \$10M Treating Hepatitis C*, Post Crescent (May 25, 2017), <http://www.postcrescent.com/story/news/investigations/2017/05/25/wisconsin-prisons-spend-10m-treating-hepatitis-c/99007788/>.

⁸¹ *Id.*

⁸² Hannah Holzer, *Not All Californians Can Get Life-saving Hepatitis C Treatment. Governor’s Budget Aims to Fix*, The Sacramento Bee (June 24, 2018), <https://www.sacbee.com/news/local/health-and-medicine/article213702989.html>.

⁸³ Ted Alcorn, *Major Milestone: Governor’s Budget Targets Hepatitis C Epidemic In Prisons*, New Mexico In Depth (Jan. 16, 2020), <http://nmindepth.com/2020/01/16/major-milestone-governors-budget-target-hepatitis-c-epidemic-in-prisons/>.

The effectiveness of DAAs has led to a standard of care of near-universal treatment and has caused a variety of organizations to update their policies and practices. Once a distant dream, elimination of the disease in our prisons—and in society as a whole—is now an attainable reality.

III. EXPANDED TREATMENT YIELDS ENORMOUS BENEFITS

Although cost is the primary justification cited by prisons that deprive their HCV-infected inmates of DAAs, the benefits far outweigh the expense for society at large. As the AASLD/IDSA guidelines note, “[t]reating inmates ultimately benefits public health because they can no longer transmit the virus to others.”⁸⁴ Further, because of the high concentration of HCV-infected Americans living in prisons, researchers have recognized the substantial public health opportunity these institutions present for eradicating the disease.⁸⁵

In one significant meta-study, researchers synthesized the results of published cost-effectiveness studies in the DAA era.⁸⁶ The results were striking. Using a range

⁸⁴ AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), <https://www.hcvguidelines.org/evaluate/when-whom>.

⁸⁵ Josiah D. Rich, et al., *Responding to Hepatitis C through the Criminal Justice System*, 370 N. Engl. J. Med. 20, 1872–74 (May 15, 2014), <http://www.natap.org/2014/HCV/nejmp1311941.pdf>, (prisons “may be the best place to efficiently identify and cure the greatest number of HCV-infected people”).

⁸⁶ See Jagpreet Chhatwal, et al., *Direct-acting Antiviral Agents for Patients with Hepatitis C Virus Genotype 1 Infection Are Cost-saving*, *Clinical Gastroenterology & Hepatology*, 827, 827–37 (2018), [https://www.cghjournal.org/article/S1542-3565\(16\)30673-5/fulltext](https://www.cghjournal.org/article/S1542-3565(16)30673-5/fulltext).

of 2017 cost assumptions, the study provided evidence not just that use of DAAs in both cirrhotic and pre-cirrhotic patients was cost-effective, but that it was even cost-saving. The difference is important. While “cost-effective” treatments produce enough benefit to merit investment at a given price threshold, “cost-saving” interventions are so effective in preventing downstream outcomes that they pay for themselves and yield a net fiscal benefit. As the study’s authors note, “not many treatments have been shown to be cost-saving in the history of medicine.”⁸⁷

Other research accords. A 2019 study observed that “[i]n terms of cost-effectiveness, treatment of HCV with highly effective DAAs improves disease burden and outcomes.”⁸⁸ Along with healthcare costs, it considered patient and caregiver time, lost earnings due to absenteeism, and lost productivity.⁸⁹ It concluded that “DAAs were cost saving in both 10- and 20-year scenarios.”⁹⁰

A 2017 study found that “treating all HCV-infected individuals is cost saving and net social benefits are over \$500 billion greater compared with limiting

⁸⁷ *Id.*

⁸⁸ T. Joseph Mattingly II et. al., *Value in Hepatitis C Virus Treatment: A Patient-Centered Cost-Effectiveness Analysis*, 38 *PharmacoEconomics* 233, 240 (2020), <https://link.springer.com/content/pdf/10.1007/s40273-019-00864-8.pdf>.

⁸⁹ *Id.* at 235.

⁹⁰ *Id.* 238–39.

treatment.”⁹¹ “Increased access to treatment . . . reduces costs for payers, as the benefits accrued from long-term reduction in prevalent and incident cases, mortality, and medical costs outweigh the cost of treatment.”⁹²

A 2016 study found that expanded screening and treatment in prisons for 10 years would prevent 12,700 new HCV infections over the next 30 years, 89% to 92% of which would have occurred in the outside community.⁹³ They would also prevent 4,200 to 11,700 liver-related deaths, 300 to 900 liver transplants, 3,000 to 8,600 cases of liver cancer, and 2,600 to 7,300 cases of cirrhosis over 30 years.⁹⁴ Notably, among liver-related deaths averted by treatment, 80% would have occurred outside prisons.⁹⁵ Costs attributable to HCV would fall by \$760 million over 30 years—with approximately 84% of the cost savings realized by the outside community—“an even better value for [society’s] money.”⁹⁶

⁹¹ Gigi A. Moreno, et al., *Value of Comprehensive HCV Treatment among Vulnerable, High-risk Populations*, 20 Elsevier 736, 738 (2017), <https://www.sciencedirect.com/science/article/pii/S1098301517300852>.

⁹² *Id.*

⁹³ Tianhua He, et al., *Prevention of Hepatitis C by Screening and Treatment in United States Prisons*, *Annals Internal Med.* at 4 (Jan. 19, 2016), <http://www.natap.org/2015/HCV/AIME201601190-M150617.pdf>.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.* at 5–6.

Moreover, the cost of DAAs has declined substantially since their introduction. A 2019 study noted that “DAAs were initially more expensive than older treatment options; however, these costs have declined substantially over time with increased competition. . . . [L]ist prices for DAAs themselves have declined drastically, from nearly \$100,000 per treatment course in 2014 to as low as \$24,000 per treatment course [in 2019].”⁹⁷

Negotiated prices are even lower. For instance, in 2019, Louisiana agreed that Gilead Sciences’s affiliate Asegua Therapeutics would serve as the state’s hepatitis C provider for its Medicaid and correctional populations for five years and would delink the price it charges for DAAs from the volume supplied.⁹⁸ Louisiana’s goal is to treat 80% of its Medicaid and correctional populations that have hepatitis C by 2024, which would result in a cost per patient of less than \$10,000.⁹⁹ In addition, federal programs can expand access to DAAs. One federal program, for example,

⁹⁷ M. Christopher Roebuck & Joshua N. Liberman, *Assessing the Burden of Illness of Chronic Hepatitis C and the Impact of Direct-acting Antiviral Use on Healthcare Costs in Medicaid*, Am. J. of Managed Care (June 18, 2019), <https://www.ajmc.com/journals/supplement/2019/burden-chronic-hepatitis-c/assessing-burden-illness-chronic-hepatitis-impact-antiviral-healthcare-costs-medicaid?p=1>.

⁹⁸ Ted Alcorn, *Louisiana’s Deal for Hepatitis C Drugs May Serve as Model*, The Wall Street Journal (Sept. 13, 2019), <https://www.wsj.com/articles/louisianas-deal-for-hepatitis-c-drugs-may-serve-as-model-11568347621>.

⁹⁹ *Id.*

allows eligible institutions to receive steep discounts on hepatitis C and HIV medications, and some states have engaged in partnerships that would allow their correctional institutions to receive those favorable rates.¹⁰⁰

Rather than alleviate the hepatitis C epidemic, Appellees' systemic, arbitrary failure to treat HCV-infected inmates ensures that, upon release, these individuals are sicker and more likely to transmit the infection to others; more likely to develop end-stage liver disease, cirrhosis, or cancer; and more likely to rely on government programs for treatment. Momentary shortsightedness should not divert society's long-term goals. Were this Court to sanction delayed treatment and prolonged disease, it would risk significant constitutional harm inside prison walls and a poorer, sicker public outside of them.

¹⁰⁰ See Dave Boucher, *New Tennessee Prison Health Contract Could Top \$473 Million, Points to Hepatitis C Plan*, *Tennessean* (Aug. 7, 2017), <https://www.tennessean.com/story/news/2017/08/07/massive-new-tennessee-prison-health-contract-points-possible-hepatitis-c-partnership/546417001/> (Tennessee awarded a prison healthcare contract to provider who “approached Vanderbilt University Medical Center about a partnership that would allow [the state] to receive favorable rates [for DAAs under the federal program]”).

CONCLUSION

The District Court's order granting summary judgment should be reversed.

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5) because it contains 6,164 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing *amici curiae* brief with the Clerk of the Court for the U.S. Court of Appeals for the Sixth Circuit by using the CM/ECF system on April 6, 2020. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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